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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,923	07/31/2003	Pierre Hoerner	045636-5070	7579
9629	7590	09/15/2004	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP			NOLAN, SANDRA M	
1111 PENNSYLVANIA AVENUE NW			ART UNIT	
WASHINGTON, DC 20004			PAPER NUMBER	

1772

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,923	HOERNER ET AL.	
	Examiner	Art Unit	
	Sandra M. Nolan	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 23-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7-31-03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims

1. Pursuant to entry of the preliminary amendment of 31 July 2003, claims 1-19 and 23-27 are pending.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 31 July 2003 was considered by the examiner.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-19 and 23-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Are the outer layers L_1 and L_2 the outermost layers of the material?

Please clarify.

6. Claims 6-8 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The E values recited have no antecedent basis in the claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-12, 14-16, 19 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicants' admission at page 1, lines 16-32 of the specification in view of Crepeau et al (US 6,391,326).

On page 1, applicants have admitted that elastomeric films having $L_1/L_2/L_3$ structures in which intermediate layer L_2 contains an active disinfectant substance dispersed in liquid droplets and L_1 and L_3 are protective layers, is known.

The admission fails to teach the droplet size, breaking stresses or thicknesses claimed.

Crepeau teaches elastomer films having chemical substances in droplets having diameters of 10 μm or more (abstract). The droplets are liquid (col. 1, lines 21-2). The films contain applicants' polymers and plasticizers (col. 7, lines 1-7). The films are used

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to make gloves, fingerstall, condoms and dressings (col. 22, lines 25-38). The active agent is used with a solvent (Figure 5, phase B). The droplets in its films assure the release of sufficient amounts of active agents (col. 2, lines 9-14).

The citations are analogous because they both deal with elastomeric films for delivering active agents.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the films of Crepeau as the intermediate layer in the films discussed on page 1 of the specification in order to assure that sufficient amounts of active agents would be released.

The motivation to employ the films of Crepeau as the intermediate layer in the films discussed on page 1 of the specification is found at col. 2, lines 9-14 of Crepeau, where the droplets in its films are taught to assure the release of sufficient amounts of active agents.

It is deemed desirable to employ films that release sufficient amounts of active agents so that the therapeutic value of the films is attained.

The selection of films having suitable breaking stress/thickness properties is deemed a matter of engineering choice, depending upon the degree of rupturability desired in the outer film layers.

Use of the films as tapes is deemed a matter of intended use and does not serve to make them patentable over films suggested by the combined citations.

The use of droplets containing different substances would be an obvious means of preventing interaction of active materials.

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10. Claims 13 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicants' admission in view of Crepeau and Hoerner et al (US- 6,020,070).

Applicants' admission and Crepeau are discussed above.

Hoerner teaches films having active agents in gel-containing layers (abstract). The films have multiple outer E layers as discussed at col. 6, lines 17-18, col. 10, lines 14-18 and shown in Figure 4 and can have multiple A, or intermediate layers (col. 10, lines 14-18). The A layers may contain different agents (col. 10, lines 24-27).

The three citations are analogous because they all deal with films for delivery of active agents.

It would have been obvious to one having ordinary skill in the art at the time of the invention to employ the gel-containing layer and the multiple outer layers of Hoerner in the films suggested by the combination of the admission and Crepeau in order to improve the flexibility of their intermediate layers.

The motivation to employ the gel-containing layer of Hoerner in films suggested by the combination of the admission and Crepeau is found at col. 2, lines 56-57, where the flexibility of the Hoerner intermediate layer is taught.

It is deemed desirable to make films having flexible intermediate layers to make the films more comfortable when used in articles that will be in contact with human skin, such as gloves and condoms.

The use of multiple protective layers would be expected to provide better protection for the droplet-containing layer(s) and lessen the possibility of loss of active agents therefrom.

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Conclusion

Any inquiry concerning this communication should be addressed to Sandra M. Nolan, at telephone number 571/272-1495. She can normally be reached Monday through Thursday, from 6:30 am to 4:00 pm, Eastern Time.

If attempts to reach the examiner are unsuccessful, her supervisor, Harold Pyon, can be reached at 571/272-1498.

The fax number for patent application documents is 703/872-9306.

S. M. Nolan

S. M. Nolan
Primary Examiner
Technology Center 1700

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